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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,470	11/21/2002	Claire Marie Fraser	CHIR-0319	2853
7590	03/20/2006		EXAMINER	
Chiron Corporation Intellectual Property R440 PO Box 8097 Emeryville, CA 94662-8097			BASKAR, PADMAVATHI	
			ART UNIT	PAPER NUMBER
			1645	
DATE MAILED: 03/20/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,470

Applicant(s)

FRASER ET AL.

Examiner

Padmavathi v. Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 24-81 is/are pending in the application.
- 4a) Of the above claim(s) 3-21, 24 and 25-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response

1. Applicant's response filed on 11/28/05 is acknowledged.

Status of Claims

2. Claims 1-2 have been amended

Claims 1-21, 24 and 25-81 are pending in the application.

Claims 1-2 are elected and are under examination.

Claims 3-21, 24 and 25-81 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Sequence Rule Non-compliance withdrawn

3. In view of submission of sequence listing along with the computer readable form, the sequence rule non-compliance is withdrawn.

Specification – informalities withdrawn

4. In view of amendment to the specification, the specification informalities have been withdrawn.

Claim Rejections - 35 USC § 112 withdrawn

5. In view of amendment to Claims 1 and 2, the rejection under 35 U.S.C. 112, second paragraph is withdrawn

Claim Rejections - 35 USC § 101 maintained

6. The rejection of claims 1 and 2 under 35 U.S.C. 101, non-statutory subject matter is maintained as set forth in the previous office action.

Applicants' arguments filed on 11/28/05 have been fully considered but they are not deemed to be persuasive.

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Applicant states that the examiner rejected the claims without any explanation and failed to make a prima facie case for unpatentable subject matter.

The examiner rejected the claim based on the claim limitations and stated that the method is an unpatentable mathematical algorithm as claimed. Therefore, the method has no specific practical application as claimed. The examiner also indicated that the method does not provide a concrete, tangible and useful result. However, the examiner is responding to applicant's comments by explaining again why this method is an unpatentable subject matter. The claims are still drawn to a method which do not provide a concrete, tangible and useful result for the following reasons: (a) Searching for putative open reading frames within SEQ.ID.NO: 1 and identifying a sequence which corresponds to ORF does not generate any final result where one who practices the method would obtain an answer.

(b) The method claims merely retrieve previously known ORF sequences from databases.

(c) There is no transformation of data, or generation of a concrete, tangible and useful result.

There is no specific output step wherein any result is made available or output to a user.

Applicant is pointed to the newly available guidelines for computer-implemented inventions: To satisfy section 35 U.S.C. 101 requirements, the claim must be for a practical application of the 101 judicial exception, which can be identified in various ways:

- 1) The claimed invention "transforms" an article or physical object to a different state or thing.
- 2) The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

Practical Application That Produces a Useful, Concrete, and Tangible Result

For eligibility analysis, physical transformation "is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application." AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452. If the examiner determines that the claim does not entail the transformation of an article, then the examiner shall review the claim to determine if the claim provides a practical application that produces a useful, tangible and concrete result. In determining whether the claim is for a "practical application," the focus

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is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is "useful, tangible and concrete."

(1) "USEFUL RESULT" For an invention to be "useful" it must satisfy the utility requirement of section 101. The USPTO's official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial and (iii) credible. MPEP Sec. 2107 and Fisher, 421 F.3d at ___, 76 USPQ2d at 1230 (citing the Utility Guidelines with approval for interpretation of "specific" and "substantial

(2) "TANGIBLE RESULT". The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a Sec. 101 judicial exception, in that the process claim must set forth a practical application of that Sec. 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had "no substantial practical application."). "[A]n application of a law of nature or mathematical formula to a . . . process may well be deserving of patent protection." Diehr, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also Corning, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 ("It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted.").

(3) "CONCRETE RESULT" Another consideration is whether the invention produces a "concrete" result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. In re Swartz, 232 F.3d 862,864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is "irreproducible" claim should be rejected under section 101). The opposite of "concrete" is unrepeatable or unpredictable.

Claim Rejections - 35 USC 102 maintained

7. The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Ribot et al 1998, WO – A 9817805 (see IDS 9/9/02) is maintained for the same reasons as set forth in the previous office action.

Claims are drawn to a method for identifying an amino acid sequence, comprising the step steps of a searching for putative open reading frames or protein-coding sequences within SEQ ID NO: 1 and identifying an amino acid sequence corresponding to the searched putative open reading frames or protein-coding sequences, wherein the searching comprises the steps of searching SEQ ID NO: 1 for an initiation codon and searching for an in-frame termination codon downstream of the initiation codon.

Ribot et al disclose a method, automated DNA sequence analysis of PCR fragments using dye terminator reaction method (see page 57, lines 2-7) for identifying serogroup B amino acid sequences comprising the step of computer assisted analysis (i.e., searching see page 57, lines 5-7) for putative open reading frames (see Figure 1, SEQ.ID.NO: 6 and SEQ.ID.NO: 3) or coding an amino acid sequence within *N meningitidis* nucleotide sequence

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(prior art SEQ.ID.NO: 1). As shown in prior art SEQ ID NO: 1 the sequence comprises initiation codon (i.e., ATG see SEQ.ID.NO: 1, line 1, position 16-18) and an in-frame termination codon (see SEQ.ID.NO: 1 of prior art, position 1100 and 1148). The prior art discloses a method for searching ORFS or protein coding sequence of *Neisseria meningitidis*. Therefore, the claimed ORFS of SEQ.ID.NO: 1 are within the gene coding for NMB of the prior art. Thus the prior art anticipated the claimed invention.

Applicants' arguments filed on 11/28/05 have been fully considered but they are not deemed to be persuasive.

Applicant states that the prior art does not teach searching the entire genome of *N.meningitidis* B for ORFs instead teaches searching for putative ORFs in portions of the genome identified via transposon mutagenesis as playing a potential role in cell adhesion/invasion (for example, page 12, lined 28-29). The Examiner fails to demonstrate this via sequence alignment or any other method.

The examiner disagrees because the art teaches searching for putative ORF (i.e., one or two) within SEQ.ID.NO: 1 as stated in the rejection. Further, the limitations such as "the entire genome of *N meningitidis* B " "sequence alignment " etc are not set forth in the claims. Therefore, applicant is arguing the limitations which are not set forth in the claims. Further, the disclosed ORF is within the claimed SEQ.ID.NO: 1. Hence, the argument "putative ORFs in portions of the genome identified via transposon mutagenesis as playing a potential role in cell adhesion/invasion (for example, page 12, lined 28-29)" is not correct because the art discloses the claimed method. Therefore, the rejection is appropriate and maintained

8. The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Brodeur et al 1996, WO A 9629412 is maintained for the same reasons as set forth in the previous office action.

Brodeur et al disclose a method of (pNP2202 clone carrying 2.75kb insert) sequencing the gene coding for *Neisseria meningitidis* serogroup B surface protein (22kD see page 16 figure 1) using Taq Dye Deoxy Terminator Cycle Sequencing method (see page 41). This method comprises the step of searching (see page 42, lines 20-30) and analyzing the insert, that was sequenced in

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both directions for putative open reading frames (see prior art SEQ.ID.NO: 1 or coding an amino acid sequence) within *N. meningitidis* nucleotide sequence. As shown in prior art SEQ ID NO: 1 the sequence comprises initiation codon (i.e., ATG, see SEQ.ID.NO: 1, of prior art) and an in-frame termination codon (see TGA 1). Thus the prior art discloses a method for searching ORF or protein coding sequence of *Neisseria meningitidis*. Therefore, the claimed method for searching ORF of SEQ.ID.NO: 1 is within the method for searching a gene coding for NMB of the prior art. Thus the prior art anticipated the claimed invention.

Applicants' arguments filed on 11/28/05 have been fully considered but they are not deemed to be persuasive.

Applicant states that Brodeur does not teach searching the entire genome of NMB for ORFS but teaches the identification of a nucleotide sequence via cloning of a nucleotide sequence that corresponds to a protein of interest and then scanning an insert for ORFS. See, for example, page 41, lines 17-23. The art fails to demonstrate genes are searched for ORFs via sequence alignment or any other method.

The examiner disagrees because the limitations such as "the entire genome of *N meningitidis* B" "sequence alignment" "sequence alignment" "genes" etc are not set forth in the claims. Therefore, applicant is arguing the limitations which are not set forth in the claims. Accordingly, the argument "identification of a nucleotide sequence via cloning of a nucleotide sequence that corresponds to a protein of interest and then scanning an insert for ORFS" is not correct because the art disclosed the claimed method. Therefore, the rejection is appropriate and maintained.

New Rejections Based on Amendment

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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10. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Does a machine or something else identify the amino acid sequence corresponding to the searched putative ORF? What is involved in the method? Is the sequence (SEQ.ID.NO: 1) compared for ORFs via sequence alignment or any other method?

Remarks

11. Claims 1 and 2 are rejected.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989.

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The Right Fax number for submission of before-final amendments is (703) 872-9306. The Right Fax number for submission of after-final amendments is (703) 872-9307.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Padma Baskar Ph.D.



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